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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 39437/JMD/NT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB99/01080	International filing date (day/month/year) 08/04/1999	Priority date (day/month/year) 09/04/1998
International Patent Classification (IPC) or national classification and IPC C09J189/00		
Applicant MARS UK LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 7 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 08/11/1999	Date of completion of this report 14.06.2000
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I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-13 as originally filed

Claims, No.:

1-41 as originally filed

Drawings, sheets:

1/2-2/2 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 39-41.

because:

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☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 39-41 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-38 yes
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-38 yes
Industrial applicability (IA)	Yes:	Claims
	No:	Claims 1-38 yes

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Re Item III

The subject-matter of **claims 39-41** containing references to figures is not admissible, see Rule 6.2a) PCT and therefore the examination of the application is based on the subject-matter of claims 1- 38, only.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- D1: PATENT ABSTRACTS OF JAPAN vol. 18, no. 316 (C-1213), 16 June 1994 (1994-06-16) & JP 06 070972 A (NIPPON B X I KK), 15 March 1994 (1994-03-15) & DATABASE WPI Week 9415 Derwent Publications Ltd., London, GB; AN 123366
- D2: PATENT ABSTRACTS OF JAPAN vol. 17, no. 180 (C-1046), 8 April 1993 (1993-04-08) & JP 04 334396 A (HITACHI CHEM CO LTD), 20 November 1992 (1992-11-20) & DATABASE WPI Week 9301 Derwent Publications Ltd., London, GB; AN 5540
1. The present claims 1-3 relate to (I) a composition comprising an extensin protein and a non enzymatic bifunctional crosslinking agent (embodiment I)
The present claims 1-3 relate to (II) a composition comprising an extensin protein and the enzymatic crosslinking agent phenol oxidase and phenol hydroxylase (embodiment II)
Claim 19 relates a composition and claim 20 to a method comprising mixing an extensin protein, a specific cofactor and a phenol oxidase and optionally embodiment I
Claims 35 and 36-38 relate to a pharmaceutical composition comprising a crosslinked adhesive composition according to any of the composition claims and a kit for manufacture of an adhesive in sperate components forming such a composition.
Claims 4 and 5 relate to a method of forming an adhesive comprising admixing both embodiments I and II separately with a cofactor.
Claim 6 relates to a method of forming an adhesive comprising admixing embodiment I with a cofactor or admixing both embodiments I and II and a cofactor together.

Claims 7-18 relate to the above compositions or methods according to the above claims concerning particular embodiments.

Claims 21-34 relate to the use of a "composition or method" for binding substrates together.

2. The present application meets the requirements of Article 33 (2) PCT because the subject-matter of claims 1-38 is novel.

D1 discloses a composition for the adhesion of living body tissues which consists of an adhesive component comprising a partial hydrolysate of collagen protein and a curing component.

D2 discloses a composition comprising a marine mussel protein and an oxidase and/or an organic crosslinking agent as a biological adhesive.

D1, D2 or any other document of the search report does not disclose a composition comprising an extensin protein or a pharmaceutical composition comprising an extensin protein together with a chemical or enzymatic crosslinking agent.

None of the documents discloses a kit for manufacture of an adhesive in separate components comprising an extensin protein together with a chemical or enzymatic crosslinking agent or a method of forming an adhesive thereof by admixing the ingredients or its use in a composition or method for binding substrates together.

The subject-matter of claims 1-38 is therefore novel vis-à-vis the documents of the search report.

3. The present application meets also the requirements of Article 33 (3) PCT because the subject-matter of claims 1-38 is also inventive.

The problem of the present application may be regarded as to provide a further biological adhesive composition useful for binding substrates together in wet environments.

D2 may be regarded as closest document. D2 solves the above cited problem in a different way than in the present application i.e. by combining a marine mussel protein with an oxidase and/or an organic crosslinking agent as a biological

adhesive.

No indication was given in the prior art that a composition comprising an extensin protein together with a non enzymatic bifunctional crosslinking agent (embodiment I) or phenol oxidase and phenol hydroxylase (embodiment II) or the method of producing the composition or for binding substrates set out in claims 1-39 could be used to solve this problem.

Therefore the novelty and the presence of an inventive step could be acknowledged for the subject-matter of claims 1-38 vis- à- vis the documents of the search report.

4. The present application meets the requirements of Article 33 (4) PCT because the subject-matter of claims 1-38 is industrially applicable.

Re Item VIII:

1. Although **claims 1 and 2, claims 4-6, claims 19-20 and claims 36-38** each have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, the above claims do not meet the requirements of Article 6 PCT.

An amended set of claims defining the relevant subject-matter in terms of a minimum number of independent claims in each category followed by dependent claims covering features which are merely optional (Rule 6.4 PCT) has not been filed.

2. **Claim 21** relates to a "use of a composition or method for binding substrates" which renders the claim unclear. Although the reference to the "method" is

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superfluous since the result of the method is the composition, actually, the expression "or method" has not been deleted from the claim.

3. The expression "non-enzymatic bifunctional crosslinking agent" set out in present **claims 1, 2, 4, 5, 19, 20, 26, 37, 38** is unclear since the meaning of "non-enzymatic", of "bifunctional" and of "crosslinking agent" is unclear in this case. Moreover a "non-enzymatic bifunctional crosslinking agent" may be a "cofactor" and therefore both definitions overlap thus rendering the scope of the claims unclear.

The expression "non-enzymatic bifunctional crosslinking agent" has not been clarified e.g. by replacing it by the expression "non-enzymatic bifunctional crosslinking agent, selected from glutar aldehyde, diisocyanate or a quinone", see page 7, lines 31-33 of the description.

4. The term "trixene" employed in **claim 13** and appearing to be a registered trade mark has no precise meaning as it is not internationally accepted as a standard descriptive term, thereby rendering the definition of the subject-matter of this claim unclear (Article 6 PCT).